No. 91-674

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

CHAVES COUNTY HOME HEALTH SERVICE, INC., ALBUQUERQUE VISITING NURSING SERVICE, INC., AND BAYONNE VISITING NURSE ASSOCIATION, INC.,
Petitioners,

v.

LOUIS W. SULLIVAN, M.D.,
Secretary of Health and Human Services,
Respondent.

BRIEF OF AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMICI CURIAE:

American Hospital Association
Federation of American Health Systems
American Association of Homes for the Aging
American Federation of Home Health Agencies
Home Health Services and Staffing Association

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INTEREST OF AMICI CURIAE

The amici curiae are four national associations that represent virtually every type of facility qualifying for participation in the Medicare program as a "provider of services." 42 U.S.C. § 1395x(u).[1]

The American Hospital Association ("AHA") is the primary national membership organization of hospitals in the United States. Its membership includes approximately 5,400 hospitals and other health care institutions, as well as over 50,000 personal members. Virtually every AHA institutional member is a Medicare provider.

The Federation of American Health Systems is a national organization representing investor-owned companies that own over 1,300 hospitals and manage an additional 345 non-profit hospitals, a majority of which are Medicare and Medicaid certified.

The American Association of Homes for the Aging ("AAHA") is an association representing approximately 3,900 non-profit, long-term health care facilities ("nursing homes" or "nursing facilities") throughout the United States. Approximately 85% of AAHA's member facilities participate in the Medicare/Medicaid program.

The American Federation of Home Health Agencies ("AFHHA") is a national association representing home health agencies that participate in the Medicare program, as well as other entities and individuals who support the Medicare home health benefit. AFHHA's more than 135 Medicare-certified home health agency members include freestanding agencies, Visiting Nurse Associations, county agencies, hospital-based agencies, and members of chain organizations.

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[1] These providers all furnish services that are covered under Part A of the Medicare program which is at issue in this case, although members of these associations also provide services which are covered under Part B. Part A provides coverage for certain inpatient hospital services, post-hospital extended care services, home health and hospice services. 42 U.S.C. § 1395d(a). Part B provides coverage for certain outpatient and physicians' services. 42 U.S.C. § 1395k(a).

The Home Health Services and Staffing Association represents 16 national companies which operate approximately 700 Medicare-certified home health agencies in 46 states and the District of Columbia.

The Amici support the petition for a writ of certiorari filed in this case because the Secretary's sample adjudication scheme, as upheld by the court of appeals, jeopardizes their due process rights under the Medicare claims adjudication process to individualized factual determinations, notice and administrative and judicial review. Unless that decision is overturned, many hospitals, nursing homes and home health agencies will suffer severe financial damage and lose any meaningful opportunity for relief on appeal.[2]

STATEMENT OF THE CASE

A. The Secretary's Action

The Department of Health and Human Services' use of the sample adjudication scheme in this case represents the first instance in the 55-year history of the Social Security Act that the agency has sought to abolish the right to factual determinations, notice and appeal on individual claims under the formal claims adjudication process prescribed by the statute. The Social Security Act and its implementing regulations establish a four-step administrative process for the review and adjudication of claims: (1) an initial determination of the facts pertaining to a particular claim, (2) reconsideration of an adverse initial determination, (3) a hearing before an administrative law judge of an adverse reconsideration determination, and (4) Appeals Council review of any adverse hearing determination. *See* 42 U.S.C. §§ 405(a),(b); 20 C.F.R. §§ 404.929-404.961 A claimant who is dissatisfied at the end of the administrative review process may obtain judicial review. 42 U.S.C. § 405(g). If the Secretary decides to revise a

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[2] The consents of the parties to the filing of this brief have been filed with the Court.

determination, it must be reopened, and that determination may then be reviewed under the standard four-step process. 20 C.F.R. § 404.992.

This formal claims adjudication process has been used consistently for five decades to adjudicate coverage of claims under Title II (the Old-Age, Survivors, and Disability Insurance Program), Title XVI (the Supplemental Security Income Program) and Part A of Title XVIII (the Health Insurance for the Aged and Disabled Program or "Medicare"). *See generally Bowen v. Yuckert*, 482 U.S. 137, 141-43 (1987); *Heckler v. Day*, 467 U.S. 104, 108 (1984); *Heckler v. Ringer*, 466 U.S. 602, 606-07 (1984). *See also* K. Davis, Administrative Law Treatise § 10:3, p. 313 (2d ed. 1979).

In this case, the Secretary used an unpublished sample adjudication scheme to readjudicate and deny thousands of Medicare Part A claims that had been found covered under the formal Social Security claims adjudication process. The basis for most of the denials was the Secretary's determination that the services were not medically necessary. Although the Secretary reviewed the *sample* claims under the formal adjudication process, he projected the percentage of denied sample claims to a universe of other factually distinct claims which he readjudicated without *any* individualized factual review or determination and without even identifying the specific claims that were denied. The Secretary's sole reason for suspending the formal Social Security claims adjudication process on readjudication was that, in his view, it would not be cost effective. Petitioners' Appendix ("Pet. App.") at 5c.

B. The Proceedings Below

This action was commenced on September 29, 1986 but the district court delayed its decision for nearly four years "in hopes that further guidance might be forthcoming from the U.S. Supreme Court or a circuit court of appeals." Petitioners' Supplemental Appendix ("Pet. Supp. App.") at 3. The district court upheld the Secretary's sample adjudication scheme without any analysis of the statutory or

regulatory provisions establishing the Part A claims adjudication process and, instead, relied on decisions interpreting different adjudicatory schemes under the Medicaid statute and Part B of the Medicare Act.[3]

The court of appeals found the question "close" but held that sample adjudication could be reconciled with the requirements for case-by-case review and appeal under the Part A claims adjudication process. Pet. App. at 21a. In reaching its determination, the court correctly determined that

> (a) The issue in this case concerns exclusively the method prescribed by Congress for adjudicating coverage of Part A Medicare claims;[4]
>
> (b) The Part A claims adjudication process set forth in the Medicare statute, regulations and instructions requires individualized factual determinations based on case-by-case review, notice and appeal;[5]
>
> (c) The statute confers precisely the same rights to the Part A claims adjudication process upon individual beneficiaries and providers;[6] and
>
> (d) Neither the statute, legislative history, regulations nor agency policy statements mention the use of sampling to adjudicate unreviewed Medicare Part A claims.[7]

The court upheld the Secretary's use of sample adjudication to readjudicate previously approved claims on the assumption that the rights to individualized factual deter-

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[3] The district court found subject matter jurisdiction under 42 U.S.C. § 405(g) based upon the conclusion that Petitioners had effectively exhausted all administrative remedies. Pet. Supp. App. at 3 n.2.

[4] Pet. App. at 3a.

[5] Pet. App. at 6a, 12a-13a, 17a-18a.

[6] Pet. App. at 13a-14a, 15a.

[7] Pet. App. at 5a, 17a.

minations, notice and appeal under the Medicare Part A claims adjudication process are only available on "prepayment" review and not on "post-payment" review. Pet. App. at 6a, 15a. Although the court found no support for that distinction in the statute, legislative history or regulations, it concluded that such silence warranted deference to the agency's action. Pet. App. at 21a.

The court further held that Petitioners' constitutionally protected property interest in retaining payment for services provided to Medicare beneficiaries had not been denied without due process because they were given an opportunity to contest the denied *sample* claims and the statistical validity of the samples. Pet. App. at 18a-19a.[8]

The court also held that, despite the fact that the sample adjudication scheme was fundamentally different from the claims adjudication process set forth in the statute and regulations, it was not applied in violation of the rulemaking requirements of the Administrative Procedure Act solely because, in the court's view, it was a "longstanding and well-established practice." Pet. App. at 19a-20a.

For the same reason, the court concluded that the scheme, as set forth in HCFA Ruling 86-1, was not applied retroactively, even though the ruling was issued subsequent to the Secretary's use of sampling in this case, and was the sole authority for the final administrative determinations adverse to Petitioners. *See* Pet. App. at 19a-21a.

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[8] The court erroneously concluded that Petitioners failed to "timely and specifically challenge the statistical validity of the sample procedure as applied to them." Pet. App. at 6a, 16a, 19a. In fact, all three Petitioners challenged the statistical validity of the samples in the context of the appeals on the merits of the denied sample claims. *See, e.g.*, Am. App. at 8b. Petitioners also noted before the district court, and in their reply brief before the court of appeals, that the validity of the samples had been placed in issue. *See* Appellants' Reply Brief at p. 2 n.2, *citing* Plaintiffs' Statement of Genuine Issues.

REASONS FOR GRANTING THE WRIT

A. The Court of Appeals' Decision Conflicts With Holdings Of This Court That The Social Security Claims Adjudication Process Requires Individualized Factual Determinations, Notice and Appeal

The court of appeals' decision ignores a statutory scheme which has been recognized and upheld by this Court for twenty years. The Medicare statute incorporates the formal claims adjudication process which was prescribed by, and developed under, Title II of the Social Security Act. *See* 42 U.S.C. §§ 405(a)(b),(g) as incorporated by 42 U.S.C. § 1395ff, 1395ii. *See also Heckler v. Ringer*, 466 U.S. 602 606-07 (1984). The four-step claims adjudication process leading to judicial review was established as early as February 1947 for the adjudication and review of claims arising under Title II. 12 Fed. Reg. 570 (1947). That process was incorporated into Title XVIII in 1965 but made available only to Medicare beneficiaries for determinations of coverage under Part A. Pub. L. No. 89-97, § 102 (1965), *codified at* 42 U.S.C. § 1395ff(b). *See* 42 C.F.R. §§ 405.701-405.750. The Social Security claims adjudication and review process was extended to providers in 1972 for Medicare Part A claims denied for lack of medical necessity in cases where liability was not waived. Pub. L. No. 92-603, § 213(a) (1972), *codified at* 42 U.S.C. § 1395pp(d). In 1986, the process was extended to providers, beneficiaries, physicians and suppliers for claims under Part B. Pub. L. No. 99-509, § 9341(a)(1)(A-D)(1986), *codified at* 42 U.S.C. § 1395ff(a),(b).

This Court has analyzed the requirements of the formal claims adjudication process mandated under Title II at least nine times. On each occasion, the Court has observed that the process requires individualized factual determinations, notice of those determinations, and administrative and judicial review. *See Richardson v. Perales*, 402 U.S. 389, 394-98 (1971); *Mathews v. Eldridge*, 424 U.S. 319, 339-40 (1976); *Califano v. Yamasaki*, 442 U.S. 682, 687-88 (1979); *Heckler v. Campbell*, 461 U.S. 458, 468 (1983);

Heckler v. Day, 467 U.S. 104, 107-08 (1984); *Bowen v. City of New York*, 476 U.S. 467, 471-73 (1986); *Bowen v. Yuckert*, 482 U.S. at 140-43; *Schweiker v. Chilicky*, 487 U.S. 412, 424 (1988); and *Sullivan v. Zebley*, ___ U.S. ___, 110 S. Ct. 885, 888, 890 (1990). The Court has noted that the claims adjudication process required by Title II is evidence of Congress' intent to be "unusually protective" of the rights and interests of claimants. *Heckler v. Day*, 467 U.S. at 106. *See also Chilicky*, 487 U.S. at 424; *Bowen v. City of New York*, 476 U.S. at 480.

Specifically, this Court has held that individualized factual determinations and review are required under the Social Security claims adjudication process where the unique medical condition of a beneficiary must be determined based on historical facts. *Campbell*, 461 U.S. at 467-468. *Accord Zebley*, 110 S. Ct. at 890; *Bowen v. City of New York*, 476 U.S. at 485. In addition, this Court has held that both the statutory scheme and the due process clause of the Constitution require that review to include an opportunity for an oral hearing on issues of credibility which are involved in waiver of liability or waiver of recoupment determinations. *Yamasaki*, 442 U.S. at 697-98; *Eldridge*, 424 U.S. at 345.[9]

In confirming the right to individualized factual determinations under the Social Security claims adjudication process, this Court has flatly rejected the kind of administrative burden arguments advanced by the Secretary in this case. According to the Court, any decision process that fails to take into account "the infinite variety of medical conditions and combinations thereof, the varying impact of such conditions due to the claimant's individual characteristics, and the constant evolution of medical di-

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[9] The Court has noted that although the Secretary may rely on rulemaking to resolve certain "classes of issues" he may not rely on such a process to avoid making individualized determinations on facts that are unique to each beneficiary. *Campbell*, 461 U.S. at 467-68. *See also American Hospital Association v. NLRB*, ___ U.S. ___, 111 S. Ct. 1539, 1543 (1991); *Mobil Oil Exploration v. United Distrib. Co.*, ___ U.S. ___, 111 S. Ct. 615, 626 (1991).

agnostic techniques," cannot fulfill the statutory mandate for individualized factual determinations. *Zebley*, 110 S. Ct. at 896. *See also Bowen v. City of New York*, 476 U.S. at 488.[10]

As the court of appeals noted, coverage and waiver determinations under Part A require the kind of assessment of unique historical medical facts and credibility which this Court has held must be made in individualized factual determinations under the Social Security claims adjudication process.[11] Thus, the court's holding that the Secretary can readjudicate thousands of unidentified, factually distinct Medicare Part A claims without making individualized factual determinations, or even identifying the specific claims, conflicts with twenty years of unbroken Supreme Court precedent.

The court of appeals' conclusion that sample adjudication results in merely a "monetized estimate," rather than in the denial of some particular, unidentified claims outside the sample, rests on a fundamental misunderstanding of

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[10] The administrative burden of providing individualized determinations and appeals is not overwhelming since the Secretary has conceded that those rights must be afforded if a claim is denied when initially presented. Pet. App. at 8c-9c. Moreover, hearing requests for both Medicare Part A and Part B claims, without the use of sample adjudications, constituted only 4% of the total hearing requests under the Social Security claims adjudication process in fiscal 1990. Social Security Administration 1991 Annual Report to Congress, 32 (May 1991). In any event, the Petitioners do not contest the Secretary's common law right to recoup lawfully determined overpayments or the use of post-payment sample review to determine whether a particular type of claim should be reopened and individually readjudicated. In fact, the Secretary currently uses sampling in just this manner to identify inpatient hospital services for individualized determinations on post-payment review. *See* the peer review program described in *American Hospital Association v. Bowen*, 834 F.2d 1037, 1049 (D.C. Cir. 1987).

[11] Payment to a provider on behalf of a beneficiary depends upon (a) whether a specific item or service was medically necessary in view of the patient's unique medical condition (42 U.S.C. § 1395y(a)(1)) and, if not, (b) whether the provider's or the beneficiary's liability should be waived because one or both did not know that the service would not be covered (42 U.S.C. § 1395pp(a)-(c)). Pet. App. at 3a.

the Title II/Medicare Part A claims adjudication process. Pet. App. at 15a-16a.

First, and foremost, both Titles II and XVIII provide a single detailed adjudication and review process for *all* claims *regardless* of when the claim review or denial takes place. 42 U.S.C. § 1395ff(a),(b) and 405(b),(g). Under that process, the *only* method by which the Secretary can assert the existence of an overpayment based on previously paid claims is to reopen and revise individual favorable initial coverage determinations. 42 C.F.R. § 405.750. *See* 20 C.F.R. § 404.987.[12]

The court's misunderstanding of the Part A claims adjudication process led it to the erroneous conclusion that the process on reopening is somehow different than the process when claims are initially presented. Pet. App. at 15a. In fact, the regulations give providers and beneficiaries the right to seek review under the Title II/Part A claims adjudication process of any initial determination that is issued after a reopening. 42 C.F.R. §§ 405.704(b), 405.710. *See* 20 C.F.R. §§ 404.992, 404.993.[13] Therefore, the claims adjudication process under Titles II and XVIII applies *whenever* claims are adjudicated and denied, and

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[12] The Title II/Part A claims adjudication process states that providers and individuals are entitled to rely on the finality of an initial favorable determination on a claim until that initial determination is reopened and revised. 42 C.F.R. § 405.708. *See* 20 C.F.R. § 404.905. The regulations expressly state that, in the absence of such a reopening and revision, the initial determination is "final and binding." *Id. Draper v. Sullivan*, 899 F.2d 1127, 1130-31 (11th Cir. 1990); *Taylor v. Heckler*, 765 F.2d 872, 876-77 (9th Cir. 1985).

[13] *See also* Title XVIII Administrative Finality—Reopening and Revising Part A and Part B Determinations and Decisions, § 04060.060, Notice of Results of Reopening, HHS Program Operations Manual (1982):

> The right to reconsideration, review, or hearing applies to the entire determination, not just the part revised.

Thus, the "crucial gap," the fulcrum of the decision below, was not in Petitioners' position, but, rather, in the court's understanding of the Title II/Part A claims adjudication process. Pet. App. at 15a.

the Secretary cannot suspend that statutory and regulatory scheme in seeking to assess an overpayment.

B. Sample Adjudication Conflicts With The Statutory Scheme and Deprives Providers Of Their Rights To Appeal And To Receive Payment For Their Services

The statutory scheme provides that, when a claim is denied for a lack of medical necessity, providers have a right to notice and administrative and judicial appeal of those individual denied claims. 42 U.S.C. §§ 1395h(j), 1395ff(b), 1395pp(d). Congress has balanced the administrative burden of these due process rights against the need for accuracy and fairness to providers, and has provided for administrative hearings for denied Part A claims where $100 or more is in controversy and for judicial review where $1,000 or more is in controversy. 42 U.S.C. § 1395ff(b)(2).

As the court of appeals correctly noted, sample adjudication "would be inconsistent with the statute" if it supplanted this statutory scheme. Pet. App. at 6a. Yet that is precisely its effect. The Secretary used the sample adjudication scheme to erase the favorable determinations rendered under the process mandated by the statute and regulations as though they never existed. Sample adjudication was, therefore, not a supplemental process, but rather, the *exclusive* process by which denied claims were adjudicated.

The Secretary also used the sample adjudication scheme to deny claims far in excess of the amounts qualifying for administrative and judicial review and to prevent Petitioners from obtaining that review. The Secretary computed the overpayments by projecting the sample denials to the *universe* of claims but determined the amount in controversy for appeal purposes based solely on the face amount of each individual *sample* claim, many of which were below the jurisdictional amounts. Petitioners were thereby denied the opportunity for administrative hearings and judicial review on numerous sample claims used by

the Secretary to deny thousands of dollars worth of claims in the universe far in excess of the jurisdictional amount thresholds established by Congress. *See, e.g.*, Order of Appeals Council Dismissing Request for Hearing (Apr. 4, 1988). Am. App. D.

Petitioners further lost the right to appeal certain denied sample claims by aggregating them with denied claims in the universe for the same individuals, as permitted by regulation. 42 C.F.R. § 405.740(e),(f)(2). Petitioners also lost the right to appeal even those individual claims in the universe that met the jurisdictional amount requirements since the claims were unidentified. The sample adjudication scheme was thus used to disrupt the balance that Congress has struck between administrative convenience and the fairness and accuracy of the Title II/Part A claims adjudication procedures.[14]

The court of appeals' holding provides an economic incentive for the Secretary to conduct only the most cursory and inaccurate review when claims are initially presented. If he denies a claim for a provider or a beneficiary at that stage, he must provide the review and appeal rights contained in the Part A claims adjudication process. If he simply waits (2 years, a month or 10 minutes) to deny claims on post-payment review, he can ignore the providers' and beneficiaries' rights and impose the sample adjudication scheme. Thus, by simply reserving denials for post-payment review as he did in this case, the Secretary is free to deprive providers and beneficiaries of the statutory rights recognized by the court of appeals.

At least as significantly, the sample adjudication scheme also abrogates the congressionally recognized rights of

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[14] Loss of those procedures can be extremely significant for providers, as illustrated by the fact that Petitioners obtained a reversal in their favor of nearly every denied sample claim that was reviewed by an administrative law judge. Pet. at 4. The Petitioners' experience on appeal was hardly unique since a study ordered by Congress found that 76% of the denied home health claims reviewed by administrative law judges were reversed in favor of the providers. *See* Report to Congress of Advisory Commission on Medicare Home Health Care (July 1, 1989).

providers to be paid for their services. The Medicare program is a health insurance program, and where claims are denied for lack of medical necessity, providers are entitled to exercise their rights under state law to seek payment from the individual who received the services.[15] Of course, providers cannot assert their rights to payment for services when the sample adjudication scheme is used because it is impossible to determine which individuals' claims in the universe have been denied. If providers cannot be compensated, either under the Medicare health insurance program or by the patient who received the services, the uncompensated costs must be borne by other patients or the services cannot be provided.

The court of appeals' holding that the Petitioners' rights to payment were not denied is based on a misunderstanding of the statutory scheme. Pet. App. at 14a. The court incorrectly assumed that providers may only seek payment from beneficiaries when coverage is denied and the Secretary decides not to waive the beneficiaries' liability. *Id.* The statute and its legislative history clearly provide that the provider may seek payment in *any* case from an individual whose claims are denied for lack of medical necessity. 42 U.S.C. § 1395pp(b),(c); S. Rep. No. 92-1230, 92d Cong., 2d Sess. 294 (1972). The Secretary's determination with respect to waiver of the beneficiaries' liability only affects whether the Secretary will indemnify the individual for the payments to the provider. 42 U.S.C. § 1395pp(b).

Thus, the congressionally recognized rights of providers to be paid for non-covered services are simply extinguished by the Secretary's sample adjudication scheme.

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[15] These rights have been recognized by Congress, the courts and the Secretary since the inception of the Medicare program. *See* S. Rep. No. 92-1230, 92d Cong., 2d Sess. 294 (1972); *Highland District Hospital v. Sec'y of HHS*, 676 F.2d 230, 238 (6th Cir. 1982); *Alabama Hospital Ass'n v. U.S.*, 656 F.2d 606, 614-15 (Ct. Cl. 1981), *cert. denied*, 456 U.S. 943 (1982); HCFA Ruling 83-1 (1982).

C. The Court Of Appeals' Decision Conflicts With The Statutory Analysis Required By Decisions Of This Court

As this Court has held, when a court reviews an agency's construction of the statute it administers, the first step is to determine, based upon the statutory provisions at issue as well as the language and design of the statute as a whole, whether Congress has expressed its intent with respect to the precise question at issue. *Sullivan v. Everhart*, ___ U.S. ___, 110 S. Ct. at 964; *Bethesda Hospital Ass'n v. Bowen*, 485 U.S. 399, 403-07 (1988); *Chevron U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. 837, 842-44 (1984). If the intent of Congress can be clearly determined, then that intent must be given effect by the court and by the agency. *Chevron*, 467 U.S. at 842-44. If the intent of Congress cannot be determined, then the court may proceed to the second step and defer to the agency's consistent interpretation, but only so long as the court finds that it is a reasonable accommodation of conflicting policies delegated to the agency's discretion, and that accommodation is one the court finds Congress would have sanctioned. *Chevron*, 467 U.S. at 845.

The precise issue of statutory construction in this case is whether Congress intended for Part A Medicare claims to be adjudicated on an individualized basis with notice and an opportunity for administrative and judicial review of those determinations. The court agreed with Petitioners that such intent was plainly expressed in the statute. Pet. App. at 6a, 12a-13a. Having found clear congressional intent to provide for individualized determinations of Part A claims, the court could not logically assume a contrary intent for post-payment review without some hint from statutory language or legislative history.[16] Such a principle

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[16] The statutory section prescribing the Title II claims adjudication process has been amended 37 times since its enactment in 1935, and the companion sections in Title XVIII have been amended 10 times since that statute was enacted in 1965. Congress has never given the slightest indication that the Secretary is authorized to adjudicate claims

of statutory analysis would require Congress to indicate not only what it means in conferring rights but also to list everything it does not mean.

The court also failed to consider the language and design of the statute as a whole by dismissing major statutory provisions which were inconsistent with its conclusion on the grounds that they were "not implicated in this case." Pet. App. at 13a. Statutory provisions accorded such treatment included (a) the provision that requires intermediaries to furnish "the provider and the individual with respect to whom the claim is made" a written explanation of the reason for each denial and prompt notification of the resolution of any reconsideration (42 U.S.C. § 1395h(j));[17] (b) the statutory provisions that require notice to the beneficiary "in each case" where coverage is denied but a claim is paid under waiver (42 U.S.C. §§ 1395pp(a),(b)); and (c) the statutory provision that states that payment to a provider under Title XVIII shall be deemed to be payment to the individual who received the services and requires the Secretary to retain the ability to identify and recoup overpayments from the individual in cases where the overpayment cannot be recouped from the provider or where the provider was "without fault" in causing the overpayment (42 U.S.C. § 1395gg(a),(b)). The court completely ignored the statutory provisions which require individual claim denials to be identified so that a determination can be made as to whether the jurisdictional amount in controversy requirements are met. 42 U.S.C. § 1395ff(b)(2). These provisions constitute clear evidence of congressional intent to require individualized determinations and appeal.

Even if the statute were ambiguous, the Secretary's interpretation in this case would not be entitled to deference because the statute and its legislative history clearly reveal that sample adjudication is not a process that Con-

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without making a determination on the unique facts pertaining to individual beneficiaries. *See* amendments to 42 U.S.C. §§ 405, 1395ff, 1395pp.

[17] *See* similar language in 42 U.S.C. § 405(b) and 42 C.F.R. § 405.702.

gress would have sanctioned. *Chevron*, 467 U.S. at 845. The amendments that Congress has made to the claims adjudication process under Titles II and XVIII since their original enactment have been directed uniformly toward broadening review and appeal rights on individual appeals and requiring more specific notice of adjudicated facts.[18] Accordingly, the court of appeals failed to apply either step of the *Chevron* test as prescribed by this Court.

Moreover, the court of appeals' decision conflicts with holdings of this Court which state that even a permissible interpretation of the statute is entitled to no deference if it is not supported by the agency's regulations, rulings or administrative practice. *See Public Employees Retirement System of Ohio v. Betts*, 492 U.S. 158, 171-72 (1989); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 211-13 (1988). It is further well-established that courts should not defer to agency interpretations which, as in this case, are inconsistent with earlier and later pronouncements. *See EEOC v. Arabian American Oil Co*, ___ U.S. ___, 111 S. Ct. 1227, 1235 (1991), *citing Skidmore v. Swift and Co.*, 323 U.S. 134, 140 (1944).

As the court of appeals conceded, the Secretary's long-standing regulations and policy statements consistently state that individual determinations and appeals are required to adjudicate Part A Medicare claims for providers and beneficiaries. 42 C.F.R. §§ 405.701-405.750; Pet. App. at 17a. The Secretary's sample adjudication policy was not set forth in any regulation, ruling or policy statement at the time it was applied to Petitioners.[19]

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[18] *See, e.g.*, Pub. L. No. 96-265, § 305(a) (1980) amending 42 U.S.C. § 405(b) to require more specific information to be provided when a claim is denied; Pub. L. No. 100-203, § 4032(a) (1987) amending 42 U.S.C. § 1395h to the same effect; Pub. L. No. 92-603, § 213(a) (1972) amending Title XVIII to extend the Title II adjudication process to providers; and Pub. L. No. 99-509, § 9341(a)(1)(A-D) (1986) amending 42 U.S.C. § 1395ff to extend the Title II claims adjudication process to Part B claims.

[19] As the court noted, HCFA Ruling 86-1 was issued *after* the Sec-

Furthermore, the Secretary stated in a signed statement to the General Accounting Office in November 1987 that sample readjudication of Part A home health claims would violate the Medicare statute and would be contrary to the longstanding congressional interest in protecting the rights of providers. *See* Letter from Otis R. Bowen, M.D., Secretary of HHS, to Charles Bowsher, Comptroller General (November 23, 1987). Am. App. C.

There can be no more authoritative source for the agency's longstanding interpretation of the statute than its own regulations and an interpretation signed personally by the Secretary. By contrast, "[d]eference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate." *Georgetown Univ. Hosp.*, 488 U.S. at 213.[20] Accordingly, the court of appeals' decision conflicts with this Court's established precedent that deference is not owed to an unpublished interpretation of the statute advanced by government counsel which is inconsistent with both preexisting regulations as well as the Secretary's subsequent interpretation of the statute.

D. The Court of Appeals' Decision Conflicts With The Rulemaking Requirements Of The Administrative Procedure Act As Recognized By This Court

It was undisputed before the court of appeals that the Secretary's sample adjudication policy was set forth only in HCFA Ruling 86-1, that it was "a rule" as defined in the Administrative Procedure Act (5 U.S.C. § 551(4)), and that it was never published in the *Federal Register* in compliance with the rulemaking requirements (5 U.S.C.

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retary's action was taken. Pet. App. at 19a. The court failed to recognize, however, that an instruction, on which it relied, was issued even later. *See* Intermediary Manual § 3799.5 (Aug. 1986). Pet. App. at 18a, 20a.

[20] The administrative law judge in the *Albuquerque VNS* case found that the interpretation of the statute set forth in HCFA Ruling 86-1 was merely the same argument which had been previously presented by government counsel in that very proceeding and rejected in a prehearing order. *See In the Case of Albuquerque Visiting Nursing Service, Inc.*, p. 14 (Sept. 29, 1986). Am. App. at 1b-2b.

§ 553). The court found that the rule was interpretative, and therefore exempt from the rulemaking requirements, solely based on the belief that sample adjudication for Part A Medicare claims was a "longstanding practice." Pet. App. at 21a. The court was wrong on both the facts and the law.

Sample adjudication is not a longstanding practice of adjudicating Part A claims. As shown, individualized factual determinations and appeal have been required under the Title II/Part A adjudication process by statute and by the holdings of this Court for five decades. Moreover, there is absolutely no reported prior instance of the Secretary even attempting to entirely delete the individual factual determinations, notice and appeal required under that process. Neither the decision in *Mt. Sinai Hospital v. Weinberger*,[21] nor in *Daytona Beach General Hospital v. Weinberger*,[22] supports that proposition. Both of those cases arose *prior* to the effective date of the 1972 amendments which extended the rights under the Part A claims adjudication process to providers. In any event, neither decision upheld, or otherwise endorsed, the Secretary's right to use sampling to readjudicate Part A Medicare claims even prior to the 1972 amendments. *See* Am. App. 5b-6b.

The court's reliance on the decision in *Mile High Therapy Centers, Inc. v. Bowen*[23] is similarly misplaced. That case involved the application of HCFA Ruling 86-1 to *Part B* Medicare claims prior to the effective date of the 1986 amendments which extended the Title II/Part A claims adjudication process to providers, beneficiaries, physicians and suppliers filing such claims.[24] Those amendments were effective for items and services furnished beginning Jan-

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[21] 517 F.2d 329, *modified*, 522 F.2d 179 (5th Cir. 1975), *cert. denied*, 425 U.S. 935 (1976).

[22] 435 F. Supp. 891 (M.D. Fla. 1977).

[23] 735 F. Supp. 984 (D. Colo. 1988).

[24] Of course, the sections of the Carriers Manual cited in the *Mile High Therapy* decision are irrelevant for the same reason. *See* Pet. App. at 20a.

uary 1, 1987. *See* Pub. L. No. 99-509, § 9341(a)(1)(A-D) (1986).[25] Thus, the court of appeals was absolutely incorrect in relying on those cases to conclude that the sample adjudication scheme constituted a longstanding interpretation of the Title II/Part A claims adjudication process at issue in this case.

Perhaps the clearest evidence that sample adjudication was not a longstanding interpretation is that, in 1986, the GAO suggested, without legal analysis, that the Secretary *begin* using the process on post-payment review. As discussed above, Secretary Bowen formally responded to the suggestion in 1987 by stating that such a process would be prohibited by statute. Am. App. C. Clearly, neither GAO, Congress, nor the Secretary has ever understood or maintained that sample adjudication of Part A claims was a longstanding practice, and, more specifically, the Secretary understood that such a change would require a statutory amendment.

Moreover, the court of appeals applied the wrong test for determining whether rulemaking is required. It is well-established that rules which have the binding effect of law and which change established law or policy are substantive rules that must be issued in compliance with the rulemaking requirements of the Administrative Procedure Act. *Chrysler Corp. v. Brown*, 441 U.S. 281, 316-17 (1979); *General Elec. Co. v. Gilbert*, 429 U.S. 125, 141 (1976); *American Hosp. Ass'n v. Bowen*, 834 F.2d at 1045. HCFA Ruling 86-1 was clearly binding because it was issued as a "ruling" and was the sole basis for the Appeals Council's decisions dismissing Petitioners' challenges to the sample adjudication scheme. *See Zebley*, 110 S. Ct. at 885 n.9. Furthermore, the sample adjudication scheme contained in the ruling altered Petitioners' rights to individual deter-

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[25] Although Amici believe the *Mile High* decision is incorrect, Congress has indicated that, at least beginning with 1987, the Part A claims adjudication process, including individualized factual determinations, notice and appeal, also applies to the adjudication and readjudication of Part B claims.

minations, notice and appeal set forth in the regulations governing Part A claims adjudication. *See* 42 C.F.R. §§ 405.701-405.750. Accordingly, even if the sample adjudication scheme had been "longstanding," the rule which gave it the binding effect of law simply could not be used to abolish established rights of providers under lawfully issued regulations without compliance with the APA rulemaking requirements. *See* 5 U.S.C. § 553(b).

E. The Retroactive Application Of HCFA Ruling 86-1 Conflicts With This Court's Holdings

The court of appeals correctly noted that, if HCFA Ruling 86-1 "changed HHS procedures," its use would be impermissibly retroactive. Pet. App. at 19a, citing this Court's holding in *Georgetown v. Bowen*. The ruling unquestionably changed the claims adjudication process to which Petitioners were entitled in 1984 and 1985 when they were initially subjected to the sample adjudication scheme. The ruling was not issued until February 20, 1986, and by its very terms, was only to be effective "on the date of issuance." Am. App. E. Yet, counsel for the Secretary sent the ruling to the administrative law judge in the *Albuquerque VNS* case and contended that he was compelled to reverse his prior holding that sample adjudications were not authorized for Part A claims adjudication. Am. App. at 2b. As stated above, the Appeals Council also subsequently relied on HCFA Ruling 86-1 in dismissing Petitioners' challenges to sample adjudication.

Neither the court of appeals nor the Secretary suggested that there is any express statutory authority for the Secretary to issue such a retroactive rule. In the absence of express congressional authorization under the Medicare Act, such rules can have no validity. *Georgetown Univ. Hosp.*, 488 U.S. at 213. The rule is also invalid under the Administrative Procedure Act because it changed rights under the claims adjudication process retroactively. 5 U.S.C. § 551(4). *Georgetown Univ. Hosp.*, 488 U.S. at 216-217 (J. Scalia concurring); *Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987).

CONCLUSION

The court of appeals decision jeopardizes the established rights of providers, physicians, suppliers, and beneficiaries nationwide to individualized factual determinations, notice and appeal under the Social Security claims adjudication process. To date, the Secretary has abolished the rights of only the Petitioners (and their patients) under that process. Amici urge the Court to accept this case and to resolve this issue of vital importance to the nation's health system before the Secretary takes further action to implement the sample adjudication scheme.

Respectfully submitted,

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APPENDIX

APPENDIX A

STATUTORY PROVISIONS

I. The Claims Adjudication Process Under Title II

A. Rules And Regulations; Procedures

1. 42 U.S.C. § 405(a)

The Secretary shall have full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this subchapter, which are necessary or appropriate to carry out such provisions, and shall adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

B. Administrative Determination Of Entitlement To Benefits; Findings Of Fact; Hearings

1. 42 U.S.C. § 405(b)

(1) The Secretary is directed to make findings of fact, and decisions as to the rights of any individual applying for a payment under this subchapter. Any such decision by the Secretary which involves a determination of disability and which is in whole or in part unfavorable to such individual shall contain a statement of the case, in understandable language, setting forth a discussion of the evidence, and stating the Secretary's determination and the reason or reasons upon which it is based. Upon request by any such individual or upon request by a wife, divorced wife, widow, surviving divorced wife, surviving divorced mother, surviving divorced father, husband, divorced husband, widower, surviving divorced husband, child, or parent who makes a showing in writing that his or her rights may be prejudiced by any decision the Secretary has rendered, he shall give such applicant and such other indi-

vidual reasonable notice and opportunity for a hearing with respect to such decision, and, if a hearing is held, shall, on the basis of evidence adduced at the hearing, affirm, modify, or reverse his findings of fact and such decision. Any such request with respect to such a decision must be filed within sixty days after notice of such decision is received by the individual making such request. The Secretary is further authorized, on his own motion, to hold such hearings and to conduct such investigations and other proceedings as he may deem necessary or proper for the administration of this subchapter. In the course of any hearing, investigation, or other proceeding, he may administer oaths and affirmations, examine witnesses, and receive evidence. Evidence may be received at any hearing before the Secretary even though inadmissible under rules of evidence applicable to court procedure.

C. Judicial Review

1. 42 U.S.C. § 405(g)

Any individual, after any final decision of the Secretary made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Secretary may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of his answer the Secretary shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the

cause for a rehearing. The findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Secretary or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Secretary, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Secretary made for good cause shown before he files his answer, remand the case to the Secretary for further action by the Secretary, and it may at any time order additional evidence to be taken before the Secretary, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Secretary shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm his findings of fact or his decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which his action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

II. Title II Claims Adjudication Process Incorporated Into Title XVIII

A. Administrative Determinations

1. 42 U.S.C. § 1395ii

The provisions of sections 406 and 416(j), and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405, shall also apply with respect to this title to the same extent as they are applicable with respect to title II.

2. 42 U.S.C. § 1395ff(a)

The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A or part B, and any other determination with respect to a claim for benefits under part A or a claim for benefits with respect to home health services under part B shall be made by the Secretary in accordance with regulations prescribed by him.

B. Hearings and Judicial Review

1. 42 U.S.C. § 1395ff(b)

(1) Any individual dissatisfied with any determination under subsection (a) as to—

(A) whether he meets the conditions of section 426 of this Act or section 103 of the Social Security Amendments of 1965,

(B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of this title, or section 1395i-2,

(C) the amount of benefits under part A or part B (including a determination where such amount is determined to be zero), or

(D) any other denial (other than under part B of title XI) of a claim for benefits under part A or a claim for benefits with respect to home health services under part

B shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g).

* * * *

(2) Notwithstanding paragraph (1)(C) and (1)(D), in the case of a claim arising—

(A) under part A, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than $100 and judicial review shall not be available to the individual under that paragraph if the amount in controversy is less than $1,000; or

(B) under part B, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than $500 and judicial review shall not be available to the individual under that paragraph if the aggregate amount in controversy is less than $1,000.

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more claims to be aggregated if the claims involve the delivery of similar or related services to the same individual or involve common issues of law and fact arising from services furnished to two or more individuals.

C. Notice of Determinations

1. 42 U.S.C. § 1395h(j)

An agreement with an agency or organization under this section shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to such agency or organization that is denied, such agency or organization—

(1) furnish the provider and the individual with respect to whom the claim is made with a written explanation of

the denial and of the statutory or regulatory basis for the denial; and

(2) in the case of a request for reconsideration of a denial, promptly notify such individual and the provider of the disposition of such reconsideration.

D. Rights Of Providers To Appeal Denials For Lack Of Medical Necessity

1. 42 U.S.C. § 1395pp(d)

In any case arising under subsection 1395pp(b) (but without regard to whether payments have been made by the individual to the provider or other person) or subsection 1395pp(c), the provider or other person shall have the same rights that an individual has under sections 1395ff(b) and 1395u(b)(3)(C) (as may be applicable) when the amount of benefit or payment is in controversy, except that such rights may, under prescribed regulations, be exercised by such provider or other person only after the Secretary determines that the individual will not exercise such rights under such sections.

III. The Coverage And Waiver Determinations Which The Secretary Must Make Under Title XVIII

A. Coverage Determinations

1. 42 U.S.C. § 1395y(a)(1)

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

B. Waiver Determinations

1. 42 U.S.C. § 1395pp(a)

Where—

(1) a determination is made that, by reason of section 1395y(a)(1) or (9) or by reason of a coverage denial described in subsection (g), payment may not be made under part A or part B of this title for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1395u(b)(3)(B)(ii), and

(2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B,

then to the extent permitted by this title, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this title), as though section 1395y(a)(1) and section 1395y(a)(9) did not apply and as though the coverage denial described in subsection (g) had not occurred. In each such case the Secretary shall notify both such individual and such provider of services or such other person, as the case may be, of the conditions under which payment for such items or services was made and in the case of comparable situations arising thereafter with respect to such individual or such provider or such other person, each shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services. Any provider or other person furnishing items or services for which payment may not be made by reason of section 1395y(a)(1) or (9) or by reason of a coverage denial described in subsection (g) shall be deemed to have knowledge that pay-

ment cannot be made for such items or services if the claim relating to such items or services involves a case, provider or other person furnishing services, procedure, or test, with respect to which such provider or other person has been notified by the Secretary (including notification by a utilization and quality control peer review organization) that a pattern of inappropriate utilization has occurred in the past, and such provider or other person has been allowed a reasonable time to correct such inappropriate utilization.

2. 42 U.S.C. § 1395pp(b)

In any case in which the provisions of paragraphs (1) and (2) of subsection (a) are met, except that such provider or such other person, as the case may be, knew, or could be expected to know, that payment for such services or items could not be made under such part A or part B, then the Secretary shall, upon proper application filed within such time as may be prescribed in regulations, indemnify the individual (referred to in such paragraphs), for any payments received from such individual by such provider or such other person, as the case may be, for such items or services. Any payments made by the Secretary as indemnification shall be deemed to have been made to such provider or such other person, as the case may be, and shall be treated as over payments, recoverable from such provider or such other person, as the case may be, under applicable provisions of law. In each such case the Secretary shall notify such individual of the conditions under which indemnification is made and in the case of comparable situations arising thereafter with respect to such individual, he shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services. No item or service for which an individual is indemnified under this subsection shall be taken into account in applying any limitation on

the amount of items and services for which payment may be made to or on behalf of the individual under this title.

3. 42 U.S.C. § 1395pp(c)

No payments shall be made under this title in any cases in which the provisions of paragraph (1) of subsection (a) are met, but both the individual to whom the items or services were furnished and the provider of service or other person, as the case may be, who furnished the items or services knew, or could reasonably have been expected to know, that payment could not be made for items or services under part A or part B by reason of section 1395y(a)(1) or (a)(9) or by reason of a coverage denial described in subsection (g).

4. 42 U.S.C. § 1395pp(f)(1)

A home health agency which meets the applicable requirements of paragraphs (3) and (4) shall be presumed to meet the requirement of subsection (a)(2).

5. 42 U.S.C. § 1395pp(f)(2)

The presumption of paragraph (1) with respect to specific services may be rebutted by actual or imputed knowledge of the facts described in subsection (a)(2), including any of the following:

(A) Notice by the fiscal intermediary of the fact that payment may not be made under this title with respect to the services.

(B) It is clear and obvious that the provider should have known at the time the services were furnished that they were excluded from coverage.

6. 42 U.S.C. § 1395pp(f)(3)

The requirements of this paragraph are as follows:

(A) The agency complies with requirements of the Secretary under this title respecting timely submittal of bills for payment and medical documentation.

(B) The agency program has reasonable procedures to notify promptly each patient (and the patient's physician)

where it is determined that a patient is being or will be furnished items or services which are excluded from coverage under this title.

7. 42 U.S.C. § 1395pp(f)(4)

(A) The requirement of this paragraph is that, on the basis of bills submitted by a home health agency during the previous quarter, the rate of denial of bills for the agency by reason of a coverage denial described in subsection (g) does not exceed 2.5 percent, computed based on visits for home health services billed.

8. 42 U.S.C. § 1395pp(f)(6)

The Secretary shall monitor the proportion of denied bills submitted by home health agencies for which reconsideration is requested, and shall notify Congress if the proportion of denials reversed upon reconsideration increases significantly.

IV. Recovery of Overpayments Under Title XVIII

A. Payments Regarded As Made To Individual

1. 42 U.S.C. § 1395gg(a)

Any payment under this title to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

B. Recovery From Individual Or Provider

1. 42 U.S.C. § 1395gg(b)(1)-(4)

Where—

(1) more than the correct amount is paid under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that

such provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(2) any payment has been made under section 1395f(e) to a provider of services or other person for items or services furnished an individual,

proper adjustments shall be made, under regulations prescribed (after consultation with the Railroad Retirement Board) by the Secretary, by decreasing subsequent payments—

(3) to which such individual is entitled under title II of this Act or under the Railroad Retirement Act of 1974, as the case may be, or

(4) if such individual dies before such adjustment has been completed, to which any other individual is entitled under title II of this Act or under the Railroad Retirement Act of 1974, as the case may be, with respect to the wages and self-employment income or the compensation constituting the basis of the benefits of such deceased individual under title II of such Act.

As soon as practicable after any adjustment under paragraph (3) or (4) is determined to be necessary, the Secretary, for purposes of this section, section 1395i(g), and section 1395f(f), shall certify (to the Railroad Retirement Board if the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1974) the amount of the overpayment as to which the adjustment is to be made. For purposes of clause (B) of paragraph (1), such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary's determination that more than such correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid; except that the Secretary may reduce such

three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

2. 42 U.S.C. § 1395gg(c)

There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1395f(e) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII or would be against equity and good conscience. Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) of section 1395y(a) and (B) if the Secretary's determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

REGULATORY PROVISIONS

I. The Claims Adjudication Process Under Title II

A. The Process

1. Explanation Of The Administrative Review Process

20 C.F.R. § 404.900(a)

This subpart explains the procedures we follow in determining your rights under title II of the Social Security

Act. The regulations describe the process of administrative review and explain your right to judicial review after you have taken all the necessary administrative steps. These procedures apply also to persons claiming certain benefits under title XVIII of the Act (Medicare); see 42 C.F.R. § 405.701(c). The administrative review process consists of several steps, which usually must be requested within certain time periods and in the following order:

2. Initial Determination

20 C.F.R. § 404.900(a)(1)

This is a determination we make about your entitlement or your continuing entitlement to benefits or about any other matter, as discussed in § 404.902, that gives you a right to further review.

3. Reconsideration

20 C.F.R. § 404.900(a)(2)

If you are dissatisfied with an initial determination, you may ask us to reconsider it.

4. Hearing Before An Administrative Law Judge

20 C.F.R. § 404.900(a)(3)

If you are dissatisfied with the reconsideration determination, you may request a hearing before an administrative law judge.

5. Appeals Council Review

20 C.F.R. § 404.900(a)(4)

If you are dissatisfied with the decision of the administrative law judge, you may request that the Appeals Council review the decision.

6. Federal Court Review

20 C.F.R. § 404.900(a)(5)

When you have completed the steps of the administrative review process listed in paragraphs (a)(1) through

(a)(4) of this section, we will have made our final decision. If you are dissatisfied with our final decision, you may request judicial review by filing an action in a Federal district court.

B. Notice Of Initial Determination

1. 20 C.F.R. § 404.904

We shall mail a written notice of the initial determination to you at your last known address. The reasons for the initial determination and the effect of the initial determination will be stated in the notice. The notice also informs you of the right to a reconsideration. We will not mail a notice if the beneficiary's entitlement to benefits has ended because of his or her death.

C. Effect Of Initial Determinations

1. 20 C.F.R. § 404.905

An initial determination is binding unless you request a reconsideration within the stated time period, or we revise the initial determination.

D. Reconsideration

1. 20 C.F.R. § 404.907

Reconsideration is the first step in the administrative review process that we provide if you are dissatisfied with the initial determination. If you are dissatisfied with our reconsidered determination, you may request a hearing before an administrative law judge.

E. Administrative Hearing

1. 20 C.F.R. § 404.929

If you are dissatisfied with one of the determinations or decisions listed in § 404.930 you may request a hearing. The Associate Commissioner for Hearings and Appeals, or his or her delegate, shall appoint an administrative law judge to conduct the hearing. If circumstances warrant,

the Associate Commissioner, or his or her delegate, may assign your case to another administrative law judge. At the hearing you may appear in person, submit new evidence, examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she shall issue a decision based on the hearing record. If you waive your right to appear at the hearing, the administrative law judge will make a decision based on the evidence that is in the file and any new evidence that may have been submitted for consideration. .

F. Appeals Council Review

1. 20 C.F.R. § 404.967

If you or any other party is dissatisfied with the hearing decision or with the dismissal of a hearing request, you may request that the Appeals Council review that action. The Appeals Council may deny or dismiss the request for review, or it may grant the request and either issue a decision or remand the case to an administrative law judge. The Appeals Council shall notify the parties at their last known address of the action it takes.

G. Reopenings And Revisions

1. General

20 C.F.R. § 404.987(a)

Generally, if you are dissatisfied with a determination or decision made in the administrative review process, but do not request further review within the stated time period, you lose your right to further review. However, a determination or a decision made in your case may be reopened and revised. After we reopen your case, we may revise the earlier determination or decision.

2. Procedure For Reopening And Revision

20 C.F.R. § 404.987(b)

You may ask that a determination or a decision to which you were a party be revised. The conditions under which we will reopen a previous determination or decision are explained in § 404.988.

3. Good Cause

20 C.F.R. § 404.989(a)(1), (2) and (3)

We will find that there is good cause to reopen a determination or decision if—

(1) New and material evidence is furnished;

(2) A clerical error in the computation or recomputation of benefits was made; or

(3) The evidence that was considered in making the determination or decision clearly shows on its face that an error was made.

20 C.F.R. § 404.989(b)

We will not find good cause to reopen your case if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the determination or decision was made.

II. The Claims Adjudication Process Under Title XVIII

A. General

1. 42 C.F.R. § 405.701(a)

This subpart implements 42 U.S.C. § 1395ff. Section 1395ff provides that the Secretary will make determinations about the following matters, and section 1395ff(b) provides for a hearing for an individual who is dissatisfied with the Secretary's determination as to:

(1) Whether the individual is entitled to hospital insurance (Part A) or supplementary medical insurance (Part B) under title XVIII of the Act; or

(2) The amount payable under hospital insurance.

B. The Process

1. Determinations

42 C.F.R. § 405.701(b)

This subpart establishes the procedures governing initial determinations, reconsidered determinations, hearings, and final agency review, and the reopening of determinations and decisions that are applicable to matters arising under paragraph (a) of this section.

2. Title II Process Incorporated

42 C.F.R. § 405.701(c)

Subparts J and R of 20 C.F.R. Part 404 (dealing with determinations, the administrative review process and representation of parties) are also applicable to matters arising under paragraph (a) of this section, except to the extent that specific provisions are contained in this subpart.

3. Notice

42 C.F.R. § 405.702

After a request for payment under part A of title XVIII of the Act is filed with the intermediary by or on behalf of the individual who received inpatient hospital services, extended care services, or home health services, and the intermediary has ascertained whether the items and services furnished are covered under part A of title XVIII, and where appropriate, ascertained and made payment of amounts due or has ascertained that no payments were due, the individual will be notified in writing of the initial determination in his case. In addition, if the items or services furnished such individual are not covered under

part A of title XVIII by reason of § 411.15(g) or § 411.15(k) and payment may not be made for such items or services under § 411.400 only because the requirements of § 411.400(a)(2) are not met, the provider of services which furnished such items or services will be notified in writing of the initial determination in such individual's case. These notices shall be mailed to the individual and the provider of services at their last known addresses and shall state in detail the basis for the determination. Such written notices shall also inform the individual and the provider of services of their right to reconsideration of the determination if they are dissatisfied with the determination.

4. Requests For Payment By Or On Behalf Of Individuals

42 C.F.R. § 405.704(b)

An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under part A of Medicare, including a determination with respect to:

(1) The coverage of items and services furnished;

* * * *

(11) The medical necessity of services;

(12) When services are excluded from coverage as custodial care or as not reasonable and necessary, whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage;

(13) Any other issues having a present or potential effect on the amount of benefits to be paid under part A of Medicare, including a determination as to whether there has been an overpayment or underpayment of benefits paid under part A, and if so, the amount thereof; and

(14) Whether a waiver of adjustment or recovery under sections 1395gg(b) and (c) of the Act is appropriate when an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1395f(e) of the Act) has been made with respect to an individual.

5. Initial Determination With Respect To A Provider Of Services

42 C.F.R. § 405.704(c)

An initial determination with respect to a provider of services shall be a determination made on the basis of a request for payment filed by the provider under part A of Medicare on behalf of an individual who was furnished items or services by the provider, but only if the determination involves the following:

(1) A finding by the intermediary that such items or services are not covered by reason of § 411.15(g) or § 411.15(k); and

(2) A finding by the intermediary that either such individual or such provider of services, or both, knew or could reasonably have been expected to know that such items or services were excluded from coverage under the program.

6. Effect Of Initial Determinations

42 C.F.R. § 405.708(a)

The initial determination under § 405.704(a) or (b) shall be final and binding upon the individual on whose behalf payment under part A has been requested or, if such individual is deceased, upon the representative of such individual's estate, unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such individual (or the representative of such individual's estate if the individual is deceased) shall be the party to such initial determination.

42 C.F.R. § 405.708(b)

The initial determination under § 405.704(c) shall be final and binding upon the provider of services unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such provider of services shall be the party to such initial determination.

7. Reconsideration

42 C.F.R. § 405.710(a)

An individual who is a party to an initial determination, as specified in § 405.704(a) and (b), (or if such individual is deceased, the representative of such individual's estate) and who is dissatisfied with the initial determination may request a reconsideration of such determination in accordance with § 405.711 regardless of the amount in controversy.

8. Reconsideration

42 C.F.R. § 405.710(b)

A provider of services who is a party to an initial determination (as specified in § 405.704(c) and who is dissatisfied with such initial determination may request a reconsideration of such determination in accordance with § 405.711, regardless of the amount in controversy, but only if the individual on whose behalf the request for payment was made has indicated in writing that he does not intend to request reconsideration of the intermediary's initial determination on such request for payment, or if the intermediary has made a finding (see § 405.704(c)) that such individual did not know or could not reasonably have been expected to know that the expenses incurred for the items or services for which such request for payment was made were not reimbursable by reason of § 411.15(g) or § 411.15(k).

42 C.F.R. § 405.715(a)

In reconsidering an initial determination, the Health Care Financing Administration shall review such initial determination, the evidence and findings upon which such determination was based, and any additional evidence submitted to the Social Security Administration or the Health Care Financing Administration or otherwise obtained by the intermediary or the Health Care Financing Administration; and shall make a determination affirming or revising, in whole or in part, such initial determination.

42 C.F.R. § 405.715(b)

If the request for reconsideration is filed by an individual with respect to an initial determination specified in § 405.704(b)(12), the provider of services who furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto. If pursuant to § 405.710(b) a request for reconsideration is filed by a provider of services with respect to an individual determination under § 405.704(c), the individual who was furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto.

42 C.F.R. § 405.716

Written notice of the reconsidered determination shall be mailed by the Health Care Financing Administration to the parties and their representatives at their last known addresses. Such notice shall state the specific reasons for the reconsidered determination and shall advise the parties of their right to a hearing if the amount in controversy is $100 or more, or, if appropriate, advise them of the requirements for use of the expedited appeals process (see § 405.718).

9. Hearing

42 C.F.R. § 405.720(a)-(d)

A person has a right to a hearing regarding any initial determination made under § 405.704 if:

(a) Such initial determination has been reconsidered by the Health Care Financing Administration;

(b) Such person was a party to the reconsidered determination;

(c) Such person or his representative has filed a written request for a hearing in accordance with the procedure described in § 405.722; and

(d) The amount in controversy is $100 or more.

10. Appeals Council Review

42 C.F.R. § 405.724

Appeals Council review is provided by 20 C.F.R. § 404.967.

11. Determining Amount in Controversy

42 C.F.R. § 405.740(a)

The following principles shall be applicable for purposes of determining the amount in controversy:

(a) The amount in controversy should be computed as the actual amount charged the individual for the items and services in question less deductible and coinsurance amounts applicable in the particular case.

42 C.F.R. § 405.740(c)

Where the issues in dispute relate to services furnished to a patient of a provider of services, all items or services in dispute arising from a single continuous period of treatment shall be considered in determining the amount in controversy.

42 C.F.R. § 405.740(d)

The principle set forth in paragraph (c) of this section shall be applicable even when more than one request for payment is submitted, and notice of utilization issued, because of the provider's billing practices.

42 C.F.R. § 405.740(e)

Any series of posthospital home health visits shall be considered collectively in determining the amount in controversy.

20 C.F.R. § 405.740(f)(1) and (2)

Appeals from determinations pertaining to inpatient hospital services, extended care services or posthospital home health services shall not ordinarily be additive for purposes of determining the amount in controversy except, where:

(1) The denial of payment of inpatient hospital services prevents the individual from meeting a condition precedent for payment for extended care or home health services; or

(2) The same factor is at issue in more than one claim for benefits by such individual (*e.g.*, an individual, during June, is hospitalized twice; in each case the claim for payment is denied on the basis that the hospitalization occurred during an ongoing spell of illness which began prior to June and in which the individual had already utilized all available benefit days; the individual appeals claiming that he was in a new spell of illness and had the full number of benefit days available).

12. Reopening and Revision

42 C.F.R. § 405.750(a)

Reopenings concerning applications and entitlement. A determination, or decision, or revised determination or decision made by the Social Security Administration concerning any matter under § 405.704(a), may be reopened and revised under 20 C.F.R. § 404.988 (Conditions for reopening).

42 C.F.R. § 405.750(b)

Reopenings concerning a request for payment. An initial, revised, or reconsidered determination of the Health Care Financing Administration, or a decision or revised decision of a presiding officer or of the Appeals Council, with respect to an individual's rights concerning a request for payment under Part A of Medicare, which is otherwise final under 20 C.F.R. § 404.955 or 404.981 and 405.708, or 405.717 of this subpart may be reopened:

(1) Within 12 months from the date of the notice of the initial or reconsidered determination to the party to such determination;

(2) After such 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening such determination or decision (see 20 C.F.R. § 404.988(b) and 404.989); or

(3) At any time, when:

(i) Such initial, revised, or reconsidered determination or such decision or revised decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting clerical error or error on the face of the evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

APPENDIX B

Decision *In the Matter of Albuquerque Visiting* Nursing Service, Inc. (September 29, 1986) Page 13 of Decision, Joint Appendix at 60

Turning to the merits of the sampling issue, the Administrative Law Judge acknowledges that HCFA Rulings are ordinarily binding on him, within the terms of 42 C.F.R. Section 401.108(c). Still, he disputes the binding effect of Ruling No. HCFAR-86-1 in the instant case. As outlined in the letter of April 8, 1986, sent by counsel for AVNS: the ruling was not published in the Federal Register prior to issuance, as required by 5 U.S.C. Section 553 (and also by 5 U.S.C. Section 552(a)(1)(D)), which mandates such publication in the case of substantive policies; the ruling went into effect on February 20, 1986 and has not been expressly declared to have retroactive application; and a prehearing order disposing of the sampling question had already been issued with respect to AVNS well before February 20, 1986.

It should be stressed that, under 5 U.S.C. Section 552(a)(1), AVNS may not be adversely affected in any manner by a ruling required to be published in the Federal Register and not so published, except to the extent that the agency had actual and timely notice of the terms thereof. *See Los Alamitos General Hospital, Inc. v. Donnelly*, 558 F. Supp. 1141 (D.D.C. 1983); *St. John's Hickey Memorial Hospital, Inc. v. Califano*, 599 F.2d 803 (7th Cir. 1979); *Hooper v. Harris*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 34,619 (D. Conn. No. H-80-99 (M.J.B.), May 1, 1985); *Kron v. Schweiker*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 32,136 (E.D. La. No. 80-1332, Aug. 23, 1982); *Schupak M.D. d/b/a/ Queens Artificial Kidney Center v. Mathews*, Medicare and Medicaid Guide (CCH), New Developments 27,987 (D.D.C. Civ. No. 75-1109, Sept. 17, 1976); *Christian Hospital of St. Louis v. Califano*, Medi-

care and Medicaid Guide (CCH) New Developments Paragraph 28,968 (E.D. Mo. No. 76-1176-C(2), Feb. 28, 1978). It is hard to grasp how AVNS could possibly have had timely notice of Ruling HCFAR-86-1, given that notice was not received in sufficient time to enable the agency to participate in the rule-making process or to change its own policies and procedures to avoid any adverse impact from the ruling. Indeed, the rule-making provisions of the A.P.A. may not be avoided by the process of making rules in the course of an adjudicatory proceeding. *N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 89 S. Ct. 1426, 22 L.Ed.2d 709 (1969).

Moreover, counsel for AVNS voiced a valid concern in his letter of April 8, 1986 about the propriety, under 5 U.S.C. Section 554(d), of applying Ruling HCFAR-86-1 to the instant Administrative Law Judge proceeding, when the rule gives every appearance of having been issued to invest with binding authority arguments which had previously been fully considered and rejected in that proceeding by the Administrative Law Judge.

Furthermore, HCFA Rulings which conflict with the Social Security Act or with regulations promulgated thereto are invalid. *See, e.g., Tucson Medical Center v. Heckler*, 611 F. Supp. 823 (D.D.C. 1985); *St. Francis Hospital v. Heckler*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 34,918 (S.D. W. Va. No. 84-2318, Sept. 30, 1985). For, the authority of an administrative agency to make rules is not the power to make law. *See, e.g., Dixon v. United States*, 381 U.S. 68, 85 S. Ct. 1301, 14 L.Ed.2d 811 (1965). The question therefore arises whether Ruling No. HCFAR-86-1 poses a conflict with the Social Security Act or pertinent regulations.

It is evident that a conflict would exist if HCFA issued a ruling expressly and directly abrogating a provider's otherwise-existing statutory or regulatory rights to limitation of liability, to notice of initial determinations, or to ad-

ministrative or court review. What cannot be done directly cannot be done by indirection, either. *See, e.g., Anderson v. Martin*, 375 U.S. 399, 84 S. Ct. 454, 11 L.Ed.2d 430 (1964).[1] In other words, if the provider's rights to limitation of liability, notice of initial determinations, and/or review thereof apply with respect to *each separate case*, HCFA cannot foreclose invocation of those rights with respect to claims outside the sample by the simple expedient of declaring an overpayment on some proportion of those claims without first reviewing them.

Of course, the position of HCFA is that the Act and regulations afford those rights to providers only with respect to a representative sample of claims where administrative convenience warrants use of such a sample. The arguments in support of that position, as elaborated in Ruling No. HCFAR-86-1, are not persuasive.[2]

First, while the right of the government to recover monies illegally or erroneously paid out under Part A of the Medicare Program is not questioned (*Cf.* Ruling, at 4-6), and while it may well be true that "the existence of appropriate remedies to enforce that right will be presumed in the absence of a clear indication of a contrary congressional intent" (*Id.* at 6), the language of the Social Security Act is itself an indicator of congressional intent and is not

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[1] Although the aforementioned case pertains to a statutory enactment in violation of the Constitution, the principle would seem to be equally applicable to rules in conflict with statutory or regulatory provisions.

[2] Although this case is not precisely on point, as it does not involve sampling to project a Medicare Part A overpayment, counsel for AVNS, in his letter of June 12, 1986, cited *Fox v. Bowen*, Medicare and Medicaid Guide (CCH) New Developments Paragraph 35,374 (D. Conn. N. 78-541 (JAC), Apr. 23, 1986), as authority for the proposition that Medicare Part A coverage determinations must be made on an individualized basis and not on the basis of arbitrary presumptions or rules of thumb.

to be ignored. Indeed, the courts look first to the statutory language to discern the intent of Congress, and only then to the legislative history if the statutory language is unclear. *See, e.g., Blum v. Stenson*, 465 U.S. 886, 104 S. Ct. 1541, 79 L.Ed.2d 891 (1984). The plain language of 42 U.S.C. Section 1395pp(d) establishes the congressional intent against use of sampling as a remedy for the government in Part A Medicare overpayment matters.

The statutory provision reads: "*In any case* arising under Subsection (b) of this Section . . . or Subsection (c) of this Section, the provider . . . shall have *the same rights* that an individual has under Section 1395ff(b) of this title. . . ." (Emphasis added). Since an individual has a right to a hearing under Section 1395ff(b) to the same extent as is provided for in 42 U.S.C. Section 405(b) on *any* determination he is dissatisfied with regarding the amount of benefits payable under Part A (including a determination that the amount payable is zero), and since that individual also has a right to judicial review of the Secretary's final decision under 42 U.S.C. Section 405(g), so long as he meets the respective amount in controversy requirements, a provider must likewise have those rights with respect to *any* amount of benefits determination covered by Section 1395ff(b) or (c), so long as the respective amount in controversy requirements are met (and the Secretary finds that the individual affected by the determination will not exercise his own review rights).[3] Obviously, then, Section 1395pp(d) affords review rights with respect to each separate adverse qualifying determination under Sections 1395pp(b) and (c).

By the same token, as counsel for AVNS convincingly demonstrates in his pre-hearing memorandum of April 5, 1985 (at 14-15), the notice requirements spelled out in

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[3] Incidentally, a reading of Section 1395pp discloses that the terms "case" and "determination" are used interchangeably.

Sections 1395pp(a) and (b), pertaining to limitation on liability and indemnification of an individual, and the notice requirements of 42 C.F.R. Section 405.702, pertaining to initial determinations, preclude the denial of unspecified claims for services furnished to unspecified individuals. Yet, the use of sampling, by its very nature, entails such denials.

HCFA argues, in its ruling No. HCFAR-86-1 (at 5), that the courts have recognized extrapolation based on a sample as a permissible auditing method in cases arising under the Social Security Act. However, two of the cases cited in the ruling in support of that proposition—*New Jersey Welfare Rights Organization v. Cahill*, 349 F. Supp. 501 (D. N.J. 1972), and *Rosado v. Wyman*, 322 F. Supp. 1173 (E.D. N.Y. 1970), *aff'd*, 402 U.S. 991 (1971)—concerned calculation of the standard of need for AFDC purposes. Those cases are not even remotely related to the present controversy. The other two cases cited in its ruling by HCFA—*Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982), and *State of Georgia v. Califano*, 446 F. Supp. 404 (N.D. Ga. 1977)—concerned Medicaid reimbursement and not assessment of an overpayment under Medicare Part A. In addition, the *Illinois Physicians Union* case involved an express authorization of sampling under Illinois Medicaid regulations (*See* 675 F.2d, at 153); and in the *State of Georgia* case, Georgia did not argue that sampling conflicted with federal law (*Cf.* 446 F. Supp., at 406.409) and did not challenge use of sampling at any point in the administrative proceedings. (*Cf.* 446 F. Supp., at 410).[4]

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[4] Two other cases—*Mt. Sinai Medical Center v. Weinberger*, 522 F.2d 179 (5th Cir. 1975) and *Daytona Beach General Hospital v. Weinberger*, 435 F. Supp. 891 (M.D. Fla. 1977)—have also been cited by government counsel in support of sampling to determine overpayments under Medicare Part A. (See Prehearing Brief for the Health Care Financing Administration,

HCFA further argues (*see* Ruling, at 8-9) that use of sampling to calculate overpayments does not prevent providers from exercising their rights under state law to bill individuals outside the sample for items or services these individuals knew or should have known were not due them. For, a provider could supposedly request from the Intermediary or the Peer Review Organization (P.R.O.) a list of individuals outside the sample who were notified at some earlier date that they had received noncovered services of some sort. This avenue of redress is generally of little avail absent identification of the individuals outside the sample whose audited claims have been denied and absent identification of the particular items or services outside the sample being rejected. The mere fact that a person was at one time informed that the services rendered them were neither reasonable nor necessary for diagnosis or treatment of an illness or injury does not necessarily mean that subsequent services, even for the same general illness or injury, are also noncovered. AVNS cannot attempt to bill individuals named by a P.R.O. or an intermediary without incurring considerable risk. For, under 42 U.S.C. Section 1395cc(a)(2)(A), a provider of services must agree not to charge any individual for covered services (except as allowed in 42 U.S.C. Section 1395cc(a)(2), pertaining to deductibles, coinsurance amounts, etc.)

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dated April 8, 1985, at 7-8). However, as counsel for AVNS argued in his pre-hearing memorandum of April 5, 1985, at 24-29, both the *Mt. Sinai* and *Daytona Beach* cases arose prior to the enactment of 42 U.S.C. Section 1395pp. Also, the Court of Appeals in the *Mt. Sinai* case simply held that the government's common law right to recoup overpayments had not been abolished. The validity of sampling to calculate overpayment was not decided by the Court of Appeals—or, for that matter, by the District Court in its initial decision or upon remand. Finally, the *Daytona Beach* case only addressed the validity of the sample size and not of sampling, itself.

Allowing the possibility that a provider might be effectively barred from charging a beneficiary for noncovered services in at least some instances, HCFA then argues (at pp. 9-10 of the ruling) that public policy considerations favor the government's recovery of overpayments over the provider's billing interest and the government's ease in processing over the provider's stake in case-by-case auditing. The language of the ruling even suggests that a provider's objection to the use of sampling is nothing more than a bad faith attempt on the part of the provider to retain payments to which it was never legally entitled.

Still, as recognized in *Stanley v. Illinois*, 405 U.S. 645, at 657, 92 S. Ct. 1208, at 1215, 31 L.Ed. 551, at 561 (1972), there are "higher values than speed and efficiency." The undersigned Administrative Law Judge does not attempt to resolve the due process issue raised by the government's irrebuttable presumption of an overpayment for the larger universe of claims so long as any overpayment is upheld for a valid sample of claims.[5] Even so, it cannot reasonably be assumed that Congress was unmindful of the extra burden placed on HCFA and its intermediaries by 42 U.S.C. Section 1395pp, which gives providers a right to review of Medicare Part A coverage determinations. Having failed to expressly authorize sampling in the calculation of overpayments under Part A, and having expressly conferred upon providers statutory rights with respect to coverage questions which are only consistent with case-by-case consideration, Congress has itself placed those rights higher in the scale of values than the government's administrative convenience.

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[5] The due process issue in the instant case is different than that involved in *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982), or in *State of Georgia v. Califano*, 446 F. Supp. 404 (N.D. Ga. 1977), in which Illinois physicians and the State of Georgia would have been permitted to rebut the presumed overpayment by conducting a 100% audit, albeit at their own expense.

The recommended conclusions of the Administrative Law Judge are that Ruling No. HCFAR-86-1, which is in conflict with the Act and regulations, is without force and effect as to the instant case and that the Act and regulations prohibit sampling to extrapolate an overpayment against AVNS under Medicare Part A.

Page 138 of Decision, Joint Appendix at 185

Should the Appeals Council decide that sampling to project an overpayment against Albuquerque Visiting Nursing Service, Inc., is permitted under the Social Security Act and regulations promulgated thereto, the Administrative Law Judge recommends, pursuant to a request for the same by counsel for Albuquerque Visiting Nursing Service, Inc., in his letter of April 8, 1986, that the matter be remanded to an Administrative Law Judge for a supplemental hearing regarding the exact manner in which sampled cases were selected, the nature of the proprietary computer program allegedly used, and any other issues bearing on the sampling techniques which were employed and their validity.

APPENDIX C
(ADDENDUM II FROM PLAINTIFFS-APPELLANTS' BRIEF IN THE COURT OF APPEALS)

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

November 23, 1987

The Honorable Charles A. Bowsher
Comptroller General of the
United States
Washington, D.C. 20548

Dear Mr. Bowsher:

In accordance with the requirements of OMB Circular A-50, I am enclosing the Department's comments on the U.S. General Accounting Office's Report, "Medicare: Need to Strengthen Home Health Care Payment Controls and Address Unmet Needs," GAO/HRD-87-9 dated December 1986.

Sincerely,

/s/ Otis R. Bowen, M.D.
Secretary

Enclosure

Excerpt (page 4) of Department of Health and Human Services, Comments on the General Accounting Office Final Report, Need to Strengthen Home Health Care Payment Controls and Address Unmet Needs

Recommendation

That the Secretary of HHS direct the Administrator of HCFA to revise the home health postpayment utilization review program guidance to require intermediaries to use statistically valid sampling techniques for identifying and projecting the amount of noncovered care to the universe of claims paid.

Department Comment

We do not agree with this recommendation. Unlike Part B physicians claims which GAO cites as a precedent for projecting overpayments, home health agencies have certain rights which would not be available under this procedure since only sample cases are specifically identified.

Under section 1879 of the Social Security Act, payment is made for services determined to be noncovered when both the beneficiary and provider did not know or could not be reasonably expected to know that payment would not be made. The Omnibus Budget Reconciliation Act of 1981 extends this provision to services that were not formerly covered and also extends "favorable presumption" (*i.e.*, provider is deemed not to know if denial rate is below a certain percentage) to providers for these services. It would appear that there is congressional interest in protecting the providers' rights.

Under Part B, the criteria for selection for postpayment review are aberrant patterns identified through a physician profiling system. This system provides factual evidence that a physician is providing more or different services from his peers. The home health selection is based on criteria that provide no factual evidence that the providers selected

for review provide more noncovered services than other providers. In fact, existing reports support a thesis that billing of noncovered services is not limited to certain providers.

HCFA will be working closely with the home health industry to improve knowledge of Medicare coverage. Current medical review activities will be used to identify providers needing more intensive review and areas requiring more intensive provider education.

APPENDIX D
(JOINT APPENDIX 366-67)

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
SOCIAL SECURITY ADMINISTRATION
OFFICE OF HEARINGS AND APPEALS

ORDER OF APPEALS COUNCIL
DISMISSING REQUEST FOR HEARING

In case of	Claim for
Albuquerque Visiting Nursing Service Claimant	Health Insurance Benefits
Henry Roeder (Beneficiary)	472-05-6353 (Social Security Number)

This case is before the Appeals Council following receipt of a recommended decision dated September 29, 1986.

At issue is whether the Health Care Financing Administration may determine that the provider, Albuquerque Visiting Nursing Service, has been overpaid based on review of a sampling of cases. Health Care Financing Administration Ruling 86-1 directs the Social Security Administration to apply statistical sampling to project an overpayment to a provider when claims reflect that the provider has demonstrated a pattern of erroneous billing or over utilization, and when a case by case review is not administratively feasible (42 CFR 401.108). Appeals of coverage determinations may be made, but only on individually identifiable claims.

Section 405.720(d) of Regulations No. 5 (42 CFR 405.702(d)) provides that there is no right to a hearing unless the amount in controversy equals or exceeds $100.00. The amount in controversy is defined as the amount charged

the individual for the items and services in question (section 405.740, (20 CFR 405.740)). It is ascertained after the reconsidered determination. For services rendered prior to January 1, 1987, there was no provision for aggregation of the claims of two or more individuals, nor is there a regulatory provision that permits magnification of the overpayment amount in an individual case in proportion to the ratio of the total individual overpayments to the overpayment assessed against the provider.

In view of the above, the amount in controversy in this case is determined to be $44.00. The claimant's request for hearing on this case should be dismissed under the provisions of section 405.747 (42 CFR 405.747).
Accordingly, pursuant to its authority under 20 CFR 404.967, the Appeals Council hereby dismisses the request for hearing filed on October 12, 1984. The determination dated September 24, 1984, stands as the final decision of the Secretary.

Notice of this action is hereby given by mailing a copy to the provider and to the representative.

Appeals Council

/ /s/ /
Larry K. Banks, Member

/ /s/ /
Burton Berkley, Member

Date: April 4, 1988

cc:
Mrs. Muriel R. James
Executive Director
Albuquerque Visiting Nursing
Service
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APPENDIX E
(JOINT APPENDIX 13)

HCFA RULINGS

Department of Health and Human Services

Health Care Financing Administration

Ruling No. HCFAR-86-1 Date: 2/20/86

USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENT TO MEDICARE PROVIDERS AND SUPPLIERS

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex statutes or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, HCFA contractors, the Provider Reimbursement Review Board, and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This ruling, HCFAR 86-1, is the first to be issued in a format separate from the bound *HCFA Rulings* booklet or a *Federal Register* notice. HCFA is currently in the process of transferring all *HCFA Rulings* that have been issued into a looseleaf booklet form. This ruling, which is effective on the date of issuance, will be incorporated into that looseleaf booklet.